

Applicant : Lars Hellman  
Serial No. : 09/401,636  
Filed : September 22, 1999  
Page : 5

Attorney's Docket No.: 10223-006001

### REMARKS

Claims 1, 2, 4-11, and 25-54 were rejected. Claims 1, 6, 7, 25, 27, 30-33, 35, 38-41, 45-48, 50, and 52-54 have been amended herein. Thus, claims 1, 2, 4-11, and 25-54 are pending.

Claims 25, 27, 30-33, 35, 38-41, 45-48, 50, and 52-54 have been amended to recite domains. Claim 33 has been amended to recite the specific amino acid sequence of the N-terminal portion. Claims 1 and 33 have been amended to remove the "consists essentially of" language. Support for these amendments can be found throughout Applicant's specification as originally filed. For example, page 14, lines 25-30 disclose immunogenic polypeptides having CH2, CH3, and CH4 domains. Likewise, Figure 2a discloses an immunogenic polypeptide having an N-terminal portion with the amino acid sequence recited in claim 33. Thus, no new matter has been added. In addition, the title has been amended to read "Immunogenic Polypeptides for Inducing Anti-Self IgE Responses." In light of these amendments and the following remarks, Applicant respectfully requests reconsideration and allowance of claims 1, 2, 4-11, and 25-54.

#### Rejections under 35 U.S.C. § 112

The Examiner rejected claims 1, 2, 4-11, and 25-54 under 35 U.S.C. § 112, first paragraph, stating that the specification, while being enabling for "an immunogenic polypeptide comprising a non-self IgE CH2 domain, a self IgE CH3 domain, and a non-self IgE CH4 domain", does not reasonably provide enablement for:

- (A) "An immunogenic polypeptide comprising a self IgE portion and a nonself IgE portion, and wherein said self IgE portion comprises at least a portion of a CH3 domain of IgE" (claim 1),
- (B) "An immunogenic polypeptide of claim 1 wherein the nonself portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said nonself IgE portion" (claim 5),
- (C) "The immunogenic polypeptide of claim 5, wherein said first region comprises at least a portion of an IgE CH2 domain" (claim 6),
- (D) "The immunogenic polypeptide of claim 5, wherein said first region comprises at least a portion of an IgE CH4 domain" (claim 7).

Applicant : Lars Hellman  
Serial No. : 09/401,636  
Filed : September 22, 1999  
Page : 6

Attorney's Docket No.: 10223-006001

Applicant respectfully disagrees. A person having ordinary skill in the art reading Applicant's specification would have known how to make and use immunogenic polypeptides having self portions and non-self portions, whether the portions are entire domains or partial domains. To further prosecution, however, the claims have been amended to recite domains. As indicated by the Examiner, Applicant's specification enables an immunogenic polypeptide comprising a nonself IgE CH2 domain, a self IgE CH3 domain, and a nonself IgE CH4 domain.

In light of the above, Applicant respectfully requests withdrawal of the rejection of claims 1, 2, 4-11, and 25-54 under 35 U.S.C. § 112, first paragraph.

The Examiner also rejected claims 1, 2, 4-11, and 33-40 under 35 U.S.C. § 112, first paragraph, stating that they contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner stated that the term "consists essentially of" in claims 1 and 33 constitutes new matter.

Applicant respectfully disagrees. Again, page 14, lines 25-30 disclose immunogenic polypeptides having CH2, CH3, and CH4 domains, and Figure 2a discloses an immunogenic polypeptide having an N-terminal portion. Thus, a person having ordinary skill in the art reading Applicant's specification would have understood that Applicant was in possession of immunogenic polypeptides comprising, *inter alia*, a non-self IgE portion that consists essentially of a CH2 domain and a CH4 domain, or a self IgE portion that consists essentially of an N-terminal portion. To further prosecution, however, claims 1 and 33 have been amended to replace the term "consists essentially of" with the term "comprising." This amendment is fully supported by Applicant's originally filed specification. For example, original claims 6 and 7 disclose that an immunogenic polypeptide can have a non-self IgE portion that comprises at least a portion of a CH2 domain or a CH4 domain, respectively.

In light of the above, Applicant respectfully requests withdrawal of the rejection of claims 1, 2, 4-11, and 33-40 under 35 U.S.C. § 112, first paragraph.

Applicant : Lars Hellman  
Serial No. : 09/401,636  
Filed : September 22, 1999  
Page : 7

Attorney's Docket N : 10223-006001

### CONCLUSION

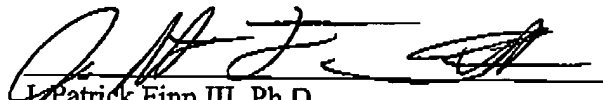
Attached is a marked-up version of the changes being made by the current amendment.

Applicant submits that the claims are in condition for allowance, which action is respectfully requested. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date:

January 23, 2002



J. Patrick Finn III, Ph.D.

Reg. No. 44,109

Fish & Richardson P.C., P.A.  
60 South Sixth Street  
Suite 3300  
Minneapolis, MN 55402  
Telephone: (612) 335-5070  
Facsimile: (612) 288-9696

60070130.doc

Applicant : Lars Hellman  
Serial No. : 09/401,636  
Filed : September 22, 1999  
Page : 8

Attorney's Docket No.: 10223-006001

**Version with markings to show changes made**

**In the specification:**

The title was amended as follows:

[ENHANCED VACCINES] IMMUNOGENIC POLYPEPTIDES FOR  
INDUCING ANTI-SELF IgE RESPONSES

**In the claims:**

Claims 1, 6, 7, 25, 27, 30-33, 35, 38-41, 45-48, 50, and 52-54 have been amended as follows:

1. (Amended Four Times) An immunogenic polypeptide, comprising a self IgE portion and a non-self IgE portion, wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal, wherein said self IgE portion comprises [at least a portion of] a CH3 domain of IgE, wherein said non-self IgE portion comprises [consists essentially of] a CH2 domain of IgE and a CH4 domain of IgE, and wherein said immunogenic polypeptide lacks a CH1 domain of IgE.

6. (Amended) The immunogenic polypeptide of claim 5, wherein said first region comprises said [at least a portion of an IgE] CH2 domain of IgE.

7. (Amended) The immunogenic polypeptide of claim 5, wherein said second region comprises said [at least a portion of an IgE] CH4 domain of IgE.

25. (Amended) An immunogenic polypeptide, comprising a self IgE domain [portion] and a non-self IgE domain [portion], wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal, wherein said self IgE domain is [portion comprises at least a portion of] a CH3 domain of IgE, and wherein said immunogenic polypeptide lacks a CH1 domain of IgE.

Applicant : Lars Hellman  
Serial No. : 09/401,636  
Filed : September 22, 1999  
Page : 9

Attorney's Docket No.: 10223-006001

27. (Amended) The immunogenic polypeptide of claim 26, wherein said non-self IgE domain [portion] comprises an IgE domain [sequence] present in a non-placental mammal.
30. (Amended) The immunogenic polypeptide of claim 25, wherein said non-self IgE domain is a CH2 domain of IgE [portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said non-self IgE portion].
31. (Amended) The immunogenic polypeptide of claim 25 [30], wherein said non-self IgE domain is a CH4 domain of IgE [first region comprises at least a portion of an IgE CH2 domain].
32. (Amended) The immunogenic polypeptide of claim 25 [30], wherein said non-self IgE domain is a CH2 domain of IgE, wherein said polypeptide further comprises a CH4 domain of IgE, said self IgE domain being located between said CH2 domain of IgE and said CH4 domain of IgE [second region comprises at least a portion of an IgE CH4 domain].
33. (Amended) An immunogenic polypeptide, comprising a self IgE portion and a non-self IgE domain [portion], wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal, [and] wherein said self IgE portion comprises [consists essentially of] an N-terminal portion of a CH3 domain of IgE, and wherein said N-terminal portion is amino acid number 117 through 178 of Figure 2a.
35. (Amended) The immunogenic polypeptide of claim 34, wherein said non-self IgE domain [portion] comprises an IgE domain [sequence] present in a non-placental mammal.
38. (Amended) The immunogenic polypeptide of claim 33, wherein said non-self IgE domain is a CH2 domain of IgE [portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said non-self IgE portion].

Applicant : Lars Hellman  
Serial No. : 09/401,636  
Filed : September 22, 1999  
Page : 10

Attorney's Docket No.: 10223-006001

39. (Amended) The immunogenic polypeptide of claim 33 [38], wherein said non-self IgE domain is a CH4 domain of IgE [first region comprises at least a portion of an IgE CH2 domain].

40. (Amended) The immunogenic polypeptide of claim 33 [38], wherein said non-self IgE domain is a CH2 domain of IgE, wherein said polypeptide further comprises a CH4 domain of IgE, said self IgE portion being located between said CH2 domain of IgE and said CH4 domain of IgE [second region comprises at least a portion of an IgE CH4 domain].

41. (Amended) An immunogenic polypeptide, comprising a self IgE domain [portion] and a non-self IgE domain [portion], wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal, and wherein said non-self IgE domain is [portion comprises] an IgE domain [sequence] present in a non-placental mammal.

45. (Amended) The immunogenic polypeptide of claim 41, wherein said non-self IgE domain is a CH2 domain of IgE [portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said non-self IgE portion].

46. (Amended) The immunogenic polypeptide of claim 41 [45], wherein said non-self IgE domain is a CH4 domain of IgE [first region comprises at least a portion of an IgE CH2 domain].

47. (Amended) The immunogenic polypeptide of claim 41 [45], wherein said non-self IgE domain is a CH2 domain of IgE, wherein said polypeptide further comprises a CH4 domain of IgE, said self IgE domain being located between said CH2 domain of IgE and said CH4 domain of IgE [second region comprises at least a portion of an IgE CH4 domain].

48. (Amended) A polypeptide, comprising a self IgE domain [portion] and a non-self IgE domain [portion], wherein said polypeptide lacks light chain Ig sequences and is effective to

Applicant : Lars Hellman  
Serial No. : 09/401,636  
Filed : September 22, 1999  
Page : 11

Attorney's Docket No.: 10223-006001

induce an anti-self IgE response in a mammal, wherein said self IgE domain is [portion comprises at least a portion of] a CH3 domain of IgE.

50. (Amended) The polypeptide of claim 49, wherein said non-self IgE domain [portion] comprises an IgE domain [sequence] present in a non-placental mammal.

52. (Amended) The polypeptide of claim 48, wherein said non-self IgE domain is a CH2 domain of IgE [portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said non-self IgE portion].

53. (Amended) The polypeptide of claim 48 [52], wherein said non-self IgE domain is a CH4 domain of IgE [first region comprises at least a portion of an IgE CH2 domain].

54. (Amended) The polypeptide of claim 48 [52], wherein said non-self IgE domain is a CH2 domain of IgE, wherein said polypeptide further comprises a CH4 domain of IgE, said self IgE domain being located between said CH2 domain of IgE and said CH4 domain of IgE [second region comprises at least a portion of an IgE CH4 domain].